

REMARKS

Claims 1, 4-8, 12-18, and 21-24 are pending in the application. The claims are amended, such that they all pertain to dosage forms containing an antidepressant drug. Subject matter that is no longer present in the claims is not being abandoned, as Applicants reserve the right to again present claims directed to any disclosed subject matter, in this or a continuing application.

No new matter has been introduced by this amendment. Antidepressant drugs were described on page 6 of the specification, and at other locations.

Reconsideration of the claim rejections and allowance of the pending claims, in view of the following remarks, are respectfully requested.

Claim Rejections – 35 U.S.C. § 102.

Claims 1, 3-9 and 12-18 were finally rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Close et al., European Patent Application Publication 0094116 A2 ("Close") for the reasons of record. Claims 3 and 9 are no longer pending, so their rejection is moot.

As explained in Applicants' previous submissions, Close discloses analgesic compositions, such as those containing aspirin, that have enhanced dissolution in the intestinal tract. Specific compositions have aspirin and excipients in an active core; a coating over the core containing an active ingredient (e.g., additional aspirin) and an optional "dispersing aid," which assists in disrupting a coating in the environment of the intestines; and an outer enteric coating.

The present claims all are directed to compositions that contain an antidepressant drug, and these have not been mentioned by Close. Accordingly, Applicants maintain that their present claims are not anticipated by Close, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103.

Claims 10, 11, 19 and 20 were finally rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Close, discussed above, in view of Henriksen et

al., U.S. Patent No. 6,391,342 ("Henriksen"), for the reasons of record. These claims are no longer pending, so the rejection is moot.

Applicants submit that this combination does not render the present claims obvious, since neither document relates to antidepressant drug dosage forms.

Henriksen discloses preformed cores coated with a layer comprising a benzimidazole compound, a disintegrant and a surfactant, in a matrix of a melt essentially consisting of one or more esters of glycerol and fatty acids. An intermediate coating layer is provided for protecting the active ingredient from an outer enteric coating. Materials which may be used in intermediate layer include HPMC, HPC and PVP. Henriksen does not contemplate the use of an alkaline substance in the disclosed formulations. Indeed, Henriksen specifically states at column 5, lines 38-40: "When this technique is used in accordance with the invention, there is no need to use any alkaline compounds or salts for further stabilization of the benzimidazole."

Close teaches that a dispersing aid, such an alkali metal phosphate salt or an amino acid, is included in its formulations to aid in disrupting an enteric coating in the intestines. This goes against the teaching of Henriksen, discussed above, that "When this technique is used in accordance with the invention, there is no need to use any alkaline compounds or salts for further stabilization of the benzimidazole." This provides further evidence that one of skill in the art would not have sought to replace the aspirin in the formulations of Close with a benzimidazole compound from Henriksen. There is no valid reason for one having ordinary skill in the art to consider making the proposed combination, and the rejection does not have a proper legal or technical foundation.

Accordingly, Applicants maintain that the present claims are not unpatentable over Close in view of Henriksen, and reconsideration of this basis for rejection is respectfully requested.

#### CONCLUSION

It is believed that claims 1, 4-8, 12-18, and 21-24 are in condition for allowance, early notice of which would be appreciated. Please contact the

undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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